NovoRapid® Penfill®

Insulin aspart (rys)

Consumer Medicine Information

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This leaflet answers some common questions about NovoRapid® Penfill®. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoRapid® Penfill® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes education nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NovoRapid® is used for

The insulin aspart, or "NovoRapid®", in NovoRapid® Penfill® is a rapid-acting insulin used to treat diabetes mellitus in adults and children. Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes – also called juvenile onset diabetes

Type 2 diabetes – also called maturity onset diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

NovoRapid® lowers your blood sugar level after injection. When injected under your skin, NovoRapid® has a faster onset of action than soluble human insulin. It takes effect within 10 to 20 minutes. Usually, the maximum effect will occur between 1-3 hours after injection and the effect may last for up to 5 hours.

As with all insulins, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. Due to its shorter duration of action, NovoRapid® has a lower risk of causing nocturnal hypoglycaemic episodes.

Penfill® is a pre-filled 3mL glass cartridge designed to be used with Novo Nordisk insulin delivery systems (such as NovoPen®).

NovoRapid® is not addictive.

NovoRapid® Penfill® is available only with a doctor's prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why NovoRapid® Penfill® has been prescribed for you.

Before you use NovoRapid® Penfill®

When you must not use it

Do not use NovoRapid® if:

1. you have an allergy to:

- any medicine containing insulin
- any of the ingredients listed in the "Ingredients" section of this leaflet

  Some of the symptoms of an allergic reaction may include:

  - redness, swelling, rash and itching at the injection site
  - rash, itching or hives on the skin
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body

2. you are experiencing a low blood sugar level (a "hypo") when the dose is due.

If you have a lot of hypos discuss appropriate treatment with your doctor.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems

Tell your doctor if you are pregnant or plan to become pregnant.

NovoRapid® can be used during pregnancy. Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure.

If you have not told your doctor about any of the above, tell them before you use NovoRapid®.

Taking other medicines

Your dose of insulin may need to change if you take other medicines. **Tell your doctor if you are currently taking any medicines, especially the following:**

- oral hypoglycaemic agents - used for the treatment of type 2 diabetes
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- alpha-blocking agents - used for the treatment of high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- non-selective beta-blocking agents - used for the treatment of certain heart conditions and high blood pressure

- angiotensin converting enzyme (ACE) inhibitors - used for the treatment of certain heart conditions, high blood pressure or elevated protein/albumin in the urine
- salicylates e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids - used to promote growth
- glucocorticoids (except when applied locally) - used to treat inflammatory conditions
- oral contraceptives ("the pill") - used for birth control
- thiazides, frusemide or ethacrynic acid - used for the treatment of high blood pressure or fluid retention (oedema)
- thyroid hormones - used for the treatment of malfunction of the thyroid gland
- sympathomimetics - used for the treatment of asthma
- sulphonamides - used to treat bacterial infections

Or other specific medicines including:

- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oxymetholone - used to treat certain blood disorders
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide – used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- diazoxide - used for the treatment of high blood pressure
- nicotinic acid - used for the treatment of high cholesterol levels in the blood
- asparaginase - used to treat leukaemia and lymph gland tumours
- quinine - used for the prevention of malaria and the relief of muscle cramps
- quinidine - used for the control of heart problems
- growth hormone - used to treat growth hormone disorders

Tell your doctor about any other medicines that you are taking.
This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use NovoRapid® Penfill®

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Your doctor may also want you to use another insulin such as Protaphane® or Levemir®.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

How much to use

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use it

NovoRapid® should normally be used immediately (up to 10 minutes) before your meal or carbohydrate snack. When necessary NovoRapid® may be used immediately after the meal.

How to use it

- NovoRapid® Penfill® is designed to be used with Novo Nordisk insulin delivery systems and NovoFine® or NovoTwist® needles.
- Carefully follow the instructions on how to use your Novo Nordisk insulin delivery system.
- Do not use the insulin level indicator on the insulin delivery system to measure your dose of NovoRapid®.
- If you use more than one type of Penfill® (more than one type of insulin), you must use a separate insulin delivery system for each type of Penfill®.
- Take care not to drop or knock the insulin delivery system that contains NovoRapid® Penfill®.
- As a precautionary measure, always carry a spare Penfill® in case your in-use Penfill® is lost or damaged.
- Inject NovoRapid® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse.
- In an emergency, the insulin contained within NovoRapid® Penfill® is suitable for intravenous administration, under medical supervision only. For emergency use, the insulin must first be withdrawn from Penfill® into a syringe. **Discard your Penfill® after emergency use.**

Checking your NovoRapid® Penfill®

Check your NovoRapid® Penfill® before each preparation and injection. Make sure you are using the correct type of insulin.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Always check the cartridge, including the rubber plunger (stopper). Do not use it if any damage is seen or if there is a gap between the plunger and the white label band.

If you note any of the above, return your Penfill® to your pharmacist – **do not use your Penfill®.**

Preparing a dose

1. Wash your hands.
2. If your NovoRapid® Penfill® is already inside your insulin delivery system, check the amount of insulin remaining. If there is insufficient insulin for your dose, follow the relevant instructions in the system user manual.
3. Alternatively, or if your insulin delivery system does not already carry a Penfill® cartridge, load a new NovoRapid® Penfill®.
4. Disinfect the rubber membrane of Penfill® with an alcohol swab.
5. Attach a NovoFine® or NovoTwist® needle.

Checking for insulin flow (priming)

Always check your Novo Nordisk insulin delivery system for insulin flow (priming) before each injection, as described in the system user manual.

The priming procedure may highlight a malfunction with your insulin delivery system. Priming also removes any air bubbles and helps indicate whether or not a needle is broken.

Only dial up your required dose after you see a drop of insulin at the needle tip.

After priming, if you need to put the insulin delivery system down, make sure the needle does not touch anything.

Injecting a dose

Choose a site for injection.

Inject NovoRapid® under the skin (subcutaneous injection) as shown by your doctor or diabetes education nurse.

NovoRapid® may be injected into the abdomen, thighs, buttocks or upper arms.

Remember to change your injection site regularly as shown to you by your doctor or diabetes education nurse.

Insert the needle into the skin, and inject the full dose of insulin under the skin.

Keep the needle under the skin for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn from the skin.

Apply gentle pressure over the injection site for several seconds.

Do not rub the area.

After injecting

Dispose of your used needle safely into a yellow plastic sharps container after each injection.

If you do not remove it, temperature changes may cause insulin to leak out of the needle.

Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles, to eliminate the risk of needlestick injury.

It is recommended that you eat a meal or a snack containing carbohydrate within 10 minutes of the injection.

Do not share needles, cartridges or insulin delivery systems.

Leave Penfill® in the insulin delivery system until it needs to be replaced.

How long to use it

Do not stop using NovoRapid® Penfill® unless your doctor tells you to.

If you use too much (overdose) - Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia or a "hypo") if you:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice , and measure your blood sugar level.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

- **to turn you on your side and get medical help immediately.**
- **not to give you anything to eat or drink.**

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause brain damage and even death.

If you miss a dose – Hyperglycaemia

If you forget your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember – *don't forget to eat some carbohydrate within 10 minutes of your injection* – and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with you doctor, diabetes education nurse or pharmacist.

While you are using NovoRapid® Penfill®

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.
If your child has diabetes it is important to tell their carers.

Keep using your insulin even if you feel well.
It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.
If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.
Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.
Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Things you must not do

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not refill your NovoRapid® Penfill®.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

If your blood sugar is low or high your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car:

- if you have frequent hypos
- if you find it hard to recognise hypoglycaemia

Tell your doctor if you drink alcohol.
Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Tell your doctor if you are ill.
Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.
Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using NovoRapid® Penfill®.

This medicine helps most people for whom it is prescribed, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (a hypo).

Tell your doctor if you notice any of the following and they worry you:

- hypos (mild to moderate)
- pain, redness, hives, bruising, swelling or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may need to stop using NovoRapid® and use another insulin.
- a depression or thickening of the skin around the injection site (lipodystrophy)
- when you first start your insulin treatment you may get visual problems or swollen hands and feet

This list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

More severe symptoms of low blood sugar levels, including:

- disorientation
- seizures, fits or convulsions
- loss of consciousness.

If a severe hypo is not treated, it can cause brain damage and death.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using NovoRapid® Penfill®

Storage

Store NovoRapid® Penfill® cartridges *that are not being used* between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).

Do not keep the NovoRapid® Penfill® *that you are using in your insulin delivery system*, or that you are carrying as a spare, in a refrigerator. You can use it up to 4 weeks below 30°C after taking it out of the refrigerator. **Discard NovoRapid® Penfill® after 4 weeks even if there is still some NovoRapid® left in it.**

The NovoRapid® in NovoRapid® Penfill® must not be frozen, or exposed to excessive heat or light. **Protect the NovoRapid® in NovoRapid® Penfill® from light by keeping the cartridges in the carton when not in use.**

Never use NovoRapid® Penfill® after the expiry date printed on the label and carton.

Never use NovoRapid® Penfill® if the solution is not clear and colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

NovoRapid® is a clear, colourless solution for subcutaneous injection. NovoRapid® Penfill® is a pre-filled 3mL glass cartridge designed to be used with Novo Nordisk insulin delivery systems.

Ingredients

NovoRapid® contains insulin aspart (rys) 100 units per mL (100 U/mL) as the active ingredient. The abbreviation "rys" indicates the method of genetic engineering used to manufacture this insulin.

NovoRapid® also contains the following inactive ingredients: glycerol, phenol, meta-cresol, zinc chloride, sodium chloride, dibasic sodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

NovoRapid® Penfill® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 3
21 Solent Circuit
Baulkham Hills NSW 2153

NovoRapid® Penfill® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

58 Richard Pearse Drive
Airport Oaks
Mangere
New Zealand.

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Further Information

For further information call the NovoCare Customer Care Centre on 1800 668 626 (Australia) or 0800 733 737 (NZ).

www.novonordisk.com.au

www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia and Diabetes New Zealand:

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au
- www.diabetes.org.nz